SmartPA Criteria Proposal

Drug/Drug Class: Anticonvulsants, Rescue Agents PDL Edit
First Implementation Date: January 21, 2021
Revised Date: January 6, 2022
Prepared For: MO HealthNet
Prepared By: MO HealthNet/Conduent
Criteria Status: ☑ Existing Criteria  ☒ Revision of Existing Criteria  ☐ New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: There are multiple FDA approved agents for the treatment of acute repetitive seizures or clusters. Diazepam rectal (Diastat®) is indicated for the management of select, refractory participants 2 years of age or older with epilepsy on stable regimens of antiepileptic drugs, who require intermittent use of diazepam to control episodes of increased seizure activity. Diazepam intranasal (Valtoco®) is indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from usual seizure pattern in epilepsy participants 6 years of age or older. Lastly, midazolam intranasal (Nayzilam®) is indicated for acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from usual seizure pattern in epilepsy participants 12 years of age or older. All three agents carry the same contraindication of acute narrow-angle glaucoma. Clinical guidelines from both the American Epilepsy Society and Neurocritical Care Society recommend diazepam rectal and midazolam intranasal when parenteral benzodiazepines are not available. These guidelines were also published prior to the approval of diazepam intranasal therefore, this agent lacks guideline recommendations.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:

<table>
<thead>
<tr>
<th>Preferred Agents</th>
<th>Non-Preferred Agents</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Diastat®</td>
<td>• Nayzilam®</td>
</tr>
<tr>
<td>• Diazepam Rectal</td>
<td></td>
</tr>
<tr>
<td>• Valtoco®</td>
<td></td>
</tr>
</tbody>
</table>

Type of Criteria:

☐ Increased risk of ADE  ☒ Preferred Drug List
☒ Appropriate Indications  ☐ Clinical Edit

Data Sources:

☐ Only Administrative Databases  ☒ Databases + Prescriber-Supplied
Setting & Population

- Drug class for review: Anticonvulsants, Rescue Agents
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Documented diagnosis of seizure disorder **AND**
  - For diazepam rectal: participants aged 2 years and older **AND**
  - For Nayzilam: participants aged 12 years and older **AND**
- Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents
  - Documented trial period for preferred agents OR
  - Documented ADE/ADR to preferred agents OR
- For Valtoco:
  - Participants aged 6 years and older **AND**
  - Documented therapeutic trial on generic diazepam rectal

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met

Required Documentation

<table>
<thead>
<tr>
<th>Laboratory Results:</th>
<th></th>
<th>Progress Notes:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>MedWatch Form:</td>
<td></td>
<td>Other:</td>
<td></td>
</tr>
</tbody>
</table>

Disposition of Edit

Denial: Exception Code “0160” (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References

10. USPDI, Micromedex; 2021.
11. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.